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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,722

09/18/2003

Lee Martin Greenberger

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10/02/2008

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EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

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DELIVERY MODE

10/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/666,722	Applicant(s) GREENBERGER ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The Requirement for a further Election of Species /Restriction

Group I requires further clarification on the species that are being elected. The Remarks/Election filed 20 December 2006 does not sufficiently establish a clear election of the species from the elected Group I.

Examiner requires the applicant to *specifically* disclose which claims are readable on the elected compound. The current claims contain an extensive disclosure of limitations of which claims are in support or suggest the claimed invention (the elected compound).

Principally, the species of claims 77, 79, and 81 have not been addressed in applicants' election.

Again, applicants' are being required to elect one specific limitation of claim 77, i.e., specific disclosure of tumor overexpression species, (e.g. MRP).

Additionally, applicants' are being required to elect a specific limitation drawn to resistance in claim 79.

Further, applicants' are being required to elect a mode of administration (e.g., concurrently).

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-68 and 73-81 are drawn to a method of treating, inhibiting the growth of, or eradicating a tumor in a mammal in need thereof wherein said tumor is resistant to at least one chemotherapeutic agent which method comprises

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providing to said mammal an effective amount of a hemiasterlin compound of Formula (II), classified in class 514 and subclass 676. If this group is elected, then the below summarized specie elections are also required.

Group II. Claims 69-72 are drawn to a process for the preparation of a carboxylic acid of the said formula, classified in class 514 and subclass 676. If this group is elected, then the below summarized specie elections are also required.

Group I is distinct from Group II in that a method of treating and a process for preparation are disclosed respectively. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct in that Group I is directed toward a practicing method of treating, inhibiting the growth of, or eradicating a tumor in a mammal. However, Group II is directed toward a process for the preparation of a carboxylic acid of disclosed formula. The Groups are related but distinct inventions in that they are not connected in at least one of: design, operation, or effect. In this instance, Groups I and II are distinct by design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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1. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

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petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

SPECIE ELECTION FOR GROUP I

Formula (II), Chemotherapeutic Agent, Tumor etiology/condition, Method/Regimen

Specie Election for Group I

This application contains claims directed to the following patentably distinct species:
Elect one exact and specific compound of Formula (II).

The species are independent or distinct because the claims encompass a multiplicity of chemical structure types, moieties, chemical formula names, etc., which are distinct one from the

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other. Instant claim 60 discloses an example of a selection of a specific moiety. It would present an undue search burden on the Examiner because of such a multiplicity of species. Therefore, Applicant must elect one exact and specific compound of Formula (II).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-59 are generic to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Second Specie Election Requirement for Group I

This application contains claims directed to the following patentably distinct species:
Elect one or an exact and specific chemotherapy agent/ antimicrotubule inhibitor or combination which will be administered with one electable Formula (II) compound. Examples are disclosed in instant claim 3 consisting of:

- a)** paclitaxel
- b)** docetaxel
- c)** vinblastine

d) vincristine

e) vinorebine

The species are independent or distinct because of various bioavailability factors, which distinguish one from the other. Additionally, a practicing co-administration with one antimicrotubule inhibitor species or a combination thereof with an electable compound of Formula (II) as disclosed presents such multiplicity in terms of susceptibilities and criteria for success. Such multiplicity would present an undue search burden on the Examiner. Therefore, Applicant must elect one exact and specific antimicrotubule inhibitor or a specifically named and clearly defined combination thereof.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-68 and 73-81 are generic to the electable species. The instant claims are directed specifically toward to an embodiment of antimicrobule inhibitors and a specific disclosure thereof (as listed above).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Third Specie Election Requirement For Group I

This application contains claims directed to the following patentably distinct species:
Elect one tumor disease/ condition, i.e., either breast, colon, lung, etc. The species are independent or distinct because of the differing etiologies and biochemical contributing factors associated with each same disease/condition. Instant claims 5-8 disclose examples of variations (e.g., tumor overexpression factors, resistance index/etiologies). Such multiplicity of factors would present an undue search burden on the Examiner. Therefore, Applicant must elect one exact and specific tumor disease/condition for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 7-55, 57-64, 66-68, 73-77, and 79-81 are generic to the above electable species. to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Fourth Specie Election Requirement for Group I

This application contains claims directed to the following patentably distinct species:
Elect one regimen method specie according to instant claims 59, 68, and 81, i.e., determine specifically wherein the compound of Formula (II) will be given **a)** before, **b)** concurrently, or **c)** after treatment with the chemotherapeutic agent. The species are independent or distinct because of the significance of the variation of concomitant administration. These three combinations are distinct because of differing and variable bioavailability factors involved with each regimen method species of administration. As a result, it would present an undue search burden on the Examiner to examine all of these factors at one. Therefore, Applicant must elect one exact and specific regimen method species of administration.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-68 and 73-81 are generic to the above electable species. Instant claims are drawn toward three embodiments of regimen therapy in terms of administration of said compound and antimicrotubule.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

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allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Specie Election Requirement for Both Groups I and II

Regardless of which Group Applicant elects, Applicant is additionally required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, in Claim I applicant is required to define “treating” and the compounds and moieties that comprise such treatment. Applicant is required to define “inhibiting the growth of” and the compounds and moieties that comprise such inhibition of growth. Applicant is required to define “eradicating” and the compounds and moieties that comprise such eradication.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617

TEB